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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,879	08/12/2002	Pieter Cornelis Langeveld	246152016800	1306
7590 Kate H Murashige Morrison & Foerster Suite 500 3811 Valley Centre Drive San Diego, CA 92130-2332	04/24/2007		EXAMINER ZEMAN, ROBERT A	ART UNIT 1645 PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/24/2007	PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/089,879	LANGEVELD ET AL.	
Examiner	Art Unit		
Robert A. Zeman	1645		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 08 February 2007.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-6 and 12-20 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-6 and 12-20 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_ .  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_\_ .

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. \_\_\_\_\_  
Applicant's submission filed on 2-8-2007 has been entered.

The amendment filed on initially filed on 10-10-2006 and entered as requested in the aforementioned request for continued examination is acknowledged. Claims 1 and 13 have been amended.

The amendment filed 2-8-2007 is acknowledged. Claims 2-6 and 12-13 have been amended. Claims 14-20 have been added. Claims 1-6 and 12-20 are pending and currently under examination.

***Claim Rejections Withdrawn***

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "compound naturally present in sample" is withdrawn in light of the amendment thereto.

The new matter rejection of claims 1-6 and 12-13 under 35 U.S.C. 112, first paragraph, based on the limitation "any compound naturally present in the sample that is capable of

inhibiting growth of the test microorganism leading to a false positive results absent said inactivating step..." is withdrawn in light of the amendment thereto.

The rejection of claims 1-6 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record is withdrawn in light of the amendment thereto.

The rejection of claims 1, 2, 4, 6 and 12 under 35 U.S.C. 102(b) as being anticipated by Charm et al. (U.S. Patent 5,354,663) is withdrawn in light of the amendment thereto. The amended claims do not disclose the addition of the test to an uncoagulated egg sample.

***Claim Rejections Maintained***

***35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-6 and 12-13 under 35 U.S.C. 102(b) based upon a public use or sale of the invention is maintained for reasons of record.

**Applicant argues:**

1. The Premi®Test procedure for antimicrobial residue in egg was not publicly disclosed until after October 4, 1999.
2. There is no evidence that the claimed was publicly used or sold in the United States.

Applicant's arguments have been fully considered and deemed non-persuasive.

While Applicant's assertion with regard to the public availability of the Premi® Test procedure for antimicrobial residue in egg is acknowledged, it is not deemed persuasive.

As stated in the MPEP:

**716.01(c) [R-2] Probative Value of Objective Evidence**

**II. ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE**

The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

See MPEP § 2145 generally for case law pertinent to the consideration of applicant's rebuttal arguments.

With regard to Point 2, Applicant's acknowledge the public availability of the Premi® Test preceding the priority date of the instant invention. The issue is when the insert detailing the alternate use of said kit became publicly known.

As outlined previously, the insert provided by Applicant is to a product named Premi® Test-egg which is a different product than that depicted in Exhibit B of Applicant's response filed on 10-7-2005. Said exhibit disclosed the use of the Premi® Test product with egg samples. The basis of the rejection is the date the Premi® Test was publicly disclosed and when the insert exemplified by Exhibit B was made publicly available. The Geijp reference was cited as evidence of the public availability of the Premi® Test. Exhibit B demonstrates that the Premi® Test constitutes the instant invention.

Moreover, the method that constitutes the instant invention is disclosed in the instruction sheet for the Premi®Test sample procedure for eggs (Exhibit B of Applicant's response filed on 10-7-2005). The procedure set forth in said instruction sheet anticipates all the limitations of the instant claims. Moreover, it is apparent the Premi®Test was publicly disclosed prior to the priority date of the instant application as evidenced by Geijp et al. (Abstract book "Third International Symposium of Hormone and Veterinary Drug Residue Analysis, Brugge", 1998).

An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows: the date the Premi®Test became publicly available. The date the insert (exemplified by Exhibit B) was originally released.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

### **35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. (U.S. Patent 5,354,663) for essentially the reasons set forth in the previous Office action in the rejection of claims 1-6 and 12.

**Applicant argues:**

1. Heating the sample prior to the addition of the test would coagulate the egg sample.
2. The process disclosed by Charm et al. and the evidence of record fails to provide a reasonable expectation of success for contacting the egg sample with the test composition prior to heating as required by the instant claims.
3. The skilled artisan would have no motivation to combine an uncoagulated egg sample with the test composition prior to heating.
4. The modification to test eggs instead of milk are neither taught nor suggested by Charm et al.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1 and 2, Charm discloses a test method for the determination of antimicrobial drugs in **food samples**, in which the test method includes placing a sample into a container and heating the sample to a temperature sufficiently high to destroy the natural inhibitors in the sample. The method further comprises adding a test microorganism to the

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sample, rapidly heat shocking said mixture; allowing said mixture to cool to (see example 1) to 80 °C to 85 °C and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, line 27, to column 4, line 10, in particular, column 3, lines 32-35).

Charm et al. differs from the instant invention in that they do not explicitly disclose the mixing of the test composition (spores) and the sample (e.g. eggs) prior to the heating steps nor do they disclose the temperature range and duration of heating encompassed by claims 5.

It would have been obvious for one of ordinary skill in the art to combine the sample with the test reagent prior to heating in order to streamline the method. The resulting method would reduce the need to handle hot samples etc. It would have been equally obvious to homogenize any solid food sample in order to ease sample handling.

One would have had a reasonable expectation of success as the disclosed method discloses the addition of the test composition to a heated sample and the test composition is not heat labile.

Moreover, it is deemed, in absence of evidence to the contrary that the combination rapid heat shock/cooling period meets the time limitation set forth in claim 5. Additionally, with regard to the specific recitation of lysozyme being the "inactivating compound" in claims 12 and 14-20, said compound would necessarily be inactivated by the performing of the modified method.

With regard to Point 4, Applicant is reminded that Charm et al. disclose that their method can be used with a variety of foodstuffs and with no exclusionary statements being made with regard to egg products.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866.

The examiner can normally be reached on Monday- Thursday, 7am-5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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ROBERT A. ZEMAN  
PRIMARY EXAMINER

April 17, 2007